

PATENT
Customer No. 22,852
Attorney Docket No. 08702.0086-00000

REMARKS

Claims 21, 23-29, and 31 are pending in the application. Claims 1-20, 22, and 30 have been cancelled without prejudice. Claims 21, 23, 26-28, and 31 have been amended to further define the claimed subject matter or to change the dependency of the claims. Support for the amendments to claims 21 and 26-28 can be found throughout the specification and specifically, e.g., at page 21, line 26 to page 22, line 27.

Applicants submit that the proposed amendments of claims 21, 23, 26-28, and 31 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

REJECTIONS UNDER 35 U.S.C. § 102

The Examiner maintained the rejection of claims 11 and 12 as allegedly anticipated by U.S. Patent No. 6,287,816 under 35 U.S.C. § 102(e) and by U.S. Patent No. 5,150,328 under 35 U.S.C. § 102(a). Claims 11 and 12 have been cancelled, removing the grounds for this rejection.

The Examiner also maintained the rejection of claims 21 and 23-31 under 35 U.S.C. § 102(a) as allegedly anticipated by WO 00/29552. The Examiner contends that

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WO 00/29552 describes compositions comprising CD105+ non-culture-expanded cells. Applicants traverse.

35 U.S.C. § 102 requires that the prior art publication teach all the limitations of the claim. WO 00/29552 does not satisfy this requirement. The currently pending claims recite CD105+ cells isolated by a single-step antibody purification process. This process differs from that discussed in WO 00/29552, which requires a two step antibody purification, where the cells are first incubated with a primary anti-MSC antibody, then isolated by incubation with an anti-Fc secondary antibody coupled to beads. In contrast, the currently claimed CD105+ cells are isolated with a single step purification process using an anti-CD105 antibody coupled directly to beads. The claimed single step purification process is more efficient and causes less cell death than the two step process of WO 00/29552. WO 00/29552 does not teach or suggest the possibility of using the one step process. Accordingly, WO 00/29552 does not describe all the limitations of the claims, and thus, does not anticipate pending claims 21, 23-29, and 31. Applicants respectfully request that the Examiner withdraw this rejection.

REJECTIONS UNDER 35 U.S.C. § 103

The Examiner maintained the rejection of claims 21 and 23-31 under 35 U.S.C. § 103(a) as allegedly obvious over WO/29552 in view of the '816 patent. The Examiner contends that non-expanded CD105+ cells are disclosed in WO 00/29552 and that, when combined with the methods of administration of BMPs described in the '816 patent, the disclosure of WO 00/29552 renders the subject matter of claims 21 and 23-31 obvious. Applicants traverse.

A prima facie case of obviousness under 35 U.S.C. § 103 has three elements.

First, the prior art references must provide a motivation to combine or modify their teachings to achieve the claimed invention. Second, the combined references must teach all the limitations of the claims. Finally, one skilled in the art must have a reasonable expectation of success in practicing the claimed invention. WO 00/29552 does not satisfy any of these elements.

First, WO 00/29552, even in combination with the '816 patent, does not provide any motivation to modify its two step antibody purification process to a one step process. In particular, WO 00/29552 does not suggest that a single step antibody purification process would result in greater efficiency or reduced cell death, both of which result from the currently claimed single step process. Without the suggestion to remove this step, WO 00/29552 does not teach all the limitations of the claims. The additional disclosure of uses for BMPs in the '816 patent does not remedy the insufficiencies of WO 00/29552 as a prior art reference. Accordingly, even the combination of WO 00/29552 with the '816 patent does not provide any motivation to modify the teachings of WO 00/29552 to reach the claimed invention, nor does the combination of the two references teach or suggest all the limitations of the claims, particularly, the single step antibody purification process.

In addition, WO 00/29552, even in view of the '816 patent, does not provide one skilled in the art with a reasonable expectation of success in practicing the invention. Specifically, neither WO 00/29552 or the '816 patent describe the actual use of non-culture-expanded cells for inducing chondrogenesis. Instead, WO 00/29552 describes one possible method for isolating non-expanded CD105+ cells. It provides no evidence

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to suggest that these non-expanded cells would actually have the ability to induce chondrogenesis, as is currently described and claimed.

For one skilled in the art to have any reasonable expectation of success in inducing chondrogenesis with non-culture-expanded cells, several characteristics of the cells would need to be shown. First, the cells need to express BMP receptors. Second, the cells need to be capable of expressing chondrogenic genes, like Sox-9. Finally, the cells need to be able to live long enough in their non-expanded state to induce the desired chondrogenic effects. WO 00/29552 does not indicate that the cells described in that publication exhibit any of these characteristics.

Instead, it is only with Applicants' disclosure that one skilled in the art would understand that the non-expanded CD105+ cells actually have the ability to induce chondrogenesis. Before Applicants disclosure, one skilled in the art would have no way of knowing that these cells would have this ability. Accordingly, WO 00/29552 does not provide one skilled in the art with a reasonable expectation of success in practicing the claimed invention.

In light of the failure of the combination of WO 00/29552 and the '816 to meet the standards for a *prima facie* case of obviousness, Applicants respectfully request that the rejection of pending claims 21, 23-29, and 31 under 35 U.S.C. § 103(a) be withdrawn.

REJECTION UNDER 35 U.S.C. § 112, 2ND PARAGRAPH

The Examiner maintained the rejection of claims 11 and 12 under 35 U.S.C. § 112, second paragraph. The Examiner contends that the recitation of "IL-1

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activity" that blocks cartilage growth in the claims is indefinite. Claims 11 and 12 have been cancelled, removing the grounds for this rejection.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge all required fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: September 7, 2004

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